



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2018-N-1214]

Medical Gas Regulation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments; public workshop

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an additional public workshop on medical gas regulation entitled "Medical Gas Regulation: Workshop III." FDA has previously held two public workshops entitled "Medical Gas Regulation: Workshop I" and "Medical Gas Regulation: Workshop II." The topic to be discussed is potential areas of Federal drug regulation that should be revised with respect to medical gases.

DATES: The public workshop will be held on May 11, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by August 9, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 (the "Great Room"), Silver Spring, MD 20993-0002. Entrance for public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInfor>

mation/ucm241740.htm. The workshop is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

You may submit comments as follows. Please note that late, untimely filed comments may not be considered. For timely consideration, we request that electronic comments on workshop topics be submitted before or within 90 days after each workshop (i.e., comments submitted by or before March 15, 2018, for Workshop I; May 10, 2018, for Workshop II; and August 9, 2018, for Workshop III). FDA has one shared docket for all workshops. However, with this notice, the docket number will change from FDA-2017-N-0001 to FDA-2018-N-1214. All comments submitted on the previous docket number will be transferred to the new docket number. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 9, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before the relevant date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-1214 for "Medical Gas Regulation." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine Kirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-2465, Fax: 301-847-8440, email: MedgasPublicWorkshops@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On May 5, 2017, President Trump signed the Consolidated Appropriations Act of 2017 (Pub. L. 115-31). Section 756 of the Consolidated Appropriations Act requires FDA to issue final regulations revising Federal drug regulations with respect to medical gases. These public workshops are being held as part of FDA's implementation of the requirements of section 756.

Since the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), FDA has engaged in multiple activities related to medical gases, including rulemaking. For example, in 2016, FDA issued the final rule "Medical Gas Containers and Closures: Current Good Manufacturing Practice Requirements" (81 FR 81685; November 18, 2016). Other activities include FDA's June 2017 revised draft guidance for industry on current good manufacturing practice for medical gases,¹ updated guidance for FDA inspectors regarding medical gases (March 2015),² an extensive review of Federal drug regulations related to medical gases from 2012 to 2014 (a report on the review was submitted to Congress in 2015),³ and implementation of FDASIA's requirements regarding certification of medical gases (to date, over 70 certifications have been granted).

FDA intends to engage in additional rulemaking in this area in accordance with section 756 of the Consolidated Appropriations Act of 2017. To conduct rulemaking as efficiently as possible, FDA intends to build on the information and stakeholder input received since

¹ Available at:
<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070270.pdf>.

² Available at:
<https://www.fda.gov/downloads/ICECI/ComplianceManuals/ComplianceProgramManual/UCM125417.pdf>.

³ Available at:
<https://www.fda.gov/downloads/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothe fdact/fdasia/ucm453727.pdf>.

FDASIA's enactment. As noted in more detail below, FDA invites comments from stakeholders on specific medical gas issues that could or should be addressed in regulation.

II. Topics for Discussion at the Public Workshops

We are holding these workshops to provide an opportunity for medical gas manufacturers and any other interested members of the public to provide input on potential areas of Federal drug regulation that should be revised with respect to medical gases.

We are asking stakeholders to comment on existing medical gas issues that, in their view, should be addressed by regulation change (rather than through other means, such as revisions to guidance or inspection practices). Commenters should include concrete and specific reasons that rulemaking is preferable to other options. Commenters' views regarding the prioritization of particular rulemaking proposals would also be helpful. As noted above, the <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 9, 2018. Late comments may not be considered.

During Workshop I (December 2017), FDA and workshop participants discussed the anticipated scope of the medical gas rulemaking, as well as three regulations to which stakeholders have previously requested changes: part 201 (21 CFR part 201) (labeling generally and labeling for medical air specifically), part 207 (21 CFR part 207) (registration and listing), and parts 210 and 211 (21 CFR parts 210 and 211) (current good manufacturing practice). A stakeholder presentation addressed parts 201, 210, and 211, among other things, including initial stakeholder views on the possibility of having one or more separate CFR sections for designated medical gases. FDA also heard comments on additional regulations and medical gas issues as time allowed.

During Workshop II (February 2018), FDA and workshop participants discussed parts 310, 314, and 514 (21 CFR parts 310, 314, and 514) (postmarket reporting of adverse drug experiences, including adverse reactions and medication errors) and the intersection of regulations for medical gases and regulations for medical devices and animal drugs. A stakeholder presentation also addressed, among other things, followup information related to Workshop I topics, including part 207 (registration and listing) and parts 210 and 211 (current good manufacturing practice), including the possibility of one or more separate CFR sections for designated medical gases, as well as additional topics including the certification process for designated medical gases and issues related to the filling of oxygen containers by emergency medical service (EMS) providers and health care facilities. FDA also heard comments on additional regulations and medical gas issues as time allowed.

The Agency has determined that we will hold a third workshop to hear additional comments from stakeholders regarding the issues discussed at Workshops I and II, as well as any additional topics related to medical gas regulation that stakeholders may wish to discuss, as time allows. This workshop is primarily intended to build on the discussion from the previous workshops, as well as written comments submitted to the docket.

During Workshop III (May 11, 2018), FDA intends to provide designated panel time for followup discussion of several topics raised at previous workshops, and for an open panel to discuss any additional issues related to medical gas regulation that are of interest to FDA or other workshop participants. The topics for designated panel time include further consideration of potential changes to: part 201 (labeling); parts 210 and 211 (current good manufacturing practice); part 207 (registration and listing); and parts 310, 314, and 514 (postmarket reporting of adverse drug experiences, including adverse reactions and medication errors); including the

possibility of one or more separate CFR sections for designated medical gases. Potential topics for open panel time include, but are not limited to: the certification process for designated medical gases; issues related to the filling of oxygen containers by EMS providers and health care facilities; or other topics of interest to stakeholders.

III. Participating in the Public Workshop

Registration and Requests for Oral Presentations: If you wish to make an oral presentation, you must register by submitting your name, title, firm name, address, telephone, email address, and Fax number to MedgasPublicWorkshops@fda.hhs.gov (see FOR FURTHER INFORMATION CONTACT) by May 4, 2018, for Workshop III. Please also indicate the type of organization you represent (e.g., industry, consumer organization) and a brief summary of your remarks (including the discussion topic(s) that you would like to address).

FDA will try to accommodate all persons who wish to make a presentation; however, the duration of each speaker's presentation may be limited by time constraints. FDA will notify registered presenters of their scheduled presentation times. Persons registered to speak should check in before the workshop and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. An agenda will be made available at least 3 days before the workshop at <https://www.fda.gov/Drugs/NewsEvents/ucm582091.htm>. FDA may also post specific questions for consideration at the meeting webpage; these will be made available at least 3 days before the workshop at <https://www.fda.gov/Drugs/NewsEvents/ucm582091.htm>.

Streaming Webcast of the Public Workshops: This public workshop will be webcast; the URL will be posted at <https://www.fda.gov/Drugs/NewsEvents/ucm582091.htm> at least 1 day before the workshop. A video record of the public workshops will be available at the same

website address for 1 year. If you need special accommodations because of a disability, please contact MedgasPublicWorkshops@fda.hhs.gov (or see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the workshop.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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